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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER AUGHENBAUGH, WALTER	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,059

Applicant(s)

SCHOENLE ET AL.

Examiner

Walter B. Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-129 is/are pending in the application.
- 4a) Of the above claim(s) 1-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 74-129 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/17/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-73, drawn to a method of making a component of a medical device, classified in class 264, subclass 405.
 - II. Claims 74-129, drawn to a component of a medical device and a tube-shaped portion of a catheter, classified in class 428, subclass 36.9.
2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as stretching and heating a sheet.
3. During a telephone conversation with Sean P. Daley on August 10, 2005 a provisional election was made without traverse to prosecute the invention of Group II, claims 74-129. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-73 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 74-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regard to claims 74-129, the specification does not indicate which polymeric materials listed in the paragraph bridging pages 12 and 13 of the specification satisfy which of the various mechanical property requirements listed on pages 2-5 of the specification.

In further regard to claims 92-103, 111, 117, Applicant does not explain in the specification how the claimed “load at break ratio” is determined. The “load at break ratio” is mentioned only on pages 2 and 5 of the specification. While the method of determining all other

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claimed properties are disclosed on pages 10-12, 14, 15 and 24-26, the method of determining the claimed "load at break ratio" is not disclosed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 74-78, 80-82, 104-109, 112-115, 118-123 and 125-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al.

In regard to claim 74, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36) of a medical device, where the component comprises a polymer having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

In regard to claim 80, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion has a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

In regard to claims 104 and 108, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36) of a medical device, where the component comprises a polymer having a hoop expansion ratio, which corresponds to the hoop stress ratio as claimed, of 3.3, 3.7 or 4.9 (col. 13, lines 14-19).

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In regard to claims 112 and 114, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion has a hoop expansion ratio, which corresponds to the hoop stress ratio as claimed, of 3.3, 3.7 or 4.9 (col. 13, lines 14-19).

In regard to claims 118 and 122, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36) of a medical device, where the component comprises a polymer having a post buckle fracture tensile strength of between about 15,000 and about 35,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed post buckle fracture tensile strength values of at least about 6500 psi and at least about 8000 psi.

In regard to claim 125 and 127, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion has a post buckle fracture tensile strength of between about 15,000 and about 35,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed post buckle fracture tensile strength values of at least about 6500 psi and at least about 8000 psi.

In regard to claims 75, 76, 105, 106, 119 and 120, Pinchuk et al. teach that the component is tube-shaped and a catheter (item 21, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36).

In regard to claims 77, 81, 107, 113, 121 and 126, Pinchuk et al. teach that the balloon can be coated with lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that the balloon comprises a first layer (the polyamide layer of Pinchuk et al.) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a

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different flexibility from the second layer (since the two layers consist of different materials, the two layer necessarily have different flexibilities).

In regard to claims 78 and 82, Pinchuk et al. teach that the tensile strength is between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 22,500 psi.

In regard to claims 109, 115, 123 and 128, Pinchuk et al. teach that the tensile strength is between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

11. Claims 84-86, 88, 89 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al.

In regard to claims 84 and 88, Sahatjian et al. teach a component (catheter including balloon, item 4, Fig. 2, item 4 shown but unlabeled in Fig. 1) of a medical device (col. 2, lines 32-35), where the component comprises a polymer having a hoop stress greater than about 36,000 psi (col. 1, lines 50-51).

In regard to claims 85 and 86, Sahatjian et al. teach that the component is tube-shaped and a catheter (col. 2, lines 32-35 and Fig. 1).

In regard to claims 89 and 91, Sahatjian et al. teach a tube-shaped portion (balloon, item 4, Fig. 2, shown but unlabeled in Fig. 1 and col. 2, lines 32-35 and 58-61) of a catheter (col. 2, lines 32-35) where the tube-shaped portion has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51).

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 79, 83, 110, 116, 124 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. in view of Sahatjian et al.

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed above. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21).

Pinchuk et al. fail to teach that the balloon has a hoop stress of at least about 3300 psi.

Sahatjian et al. teach a balloon (col. 2, lines 32-35) comprising polyamide (col. 3, lines 48-62) where the material comprising polyamide has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18). Therefore, one of ordinary skill in the art would have recognized to have used the material comprising polyamide that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyamide of the balloon of Pinchuk et al. since a material that has a hoop stress greater than about 36,000 psi is a

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well known suitable material for use as the material of a catheter balloon as taught by Sahatjian et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the material comprising polyamide that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyamide of the balloon of Pinchuk et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a catheter balloon as taught by Sahatjian et al.

14. Claims 87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. in view of Pinchuk et al.

Sahatjian et al. teach the balloon as discussed above. Sahatjian et al. teach that the balloon (col. 2, lines 32-35) comprises polyamide (col. 3, lines 48-62)

Sahatjian et al. fail to teach that the balloon comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

Conclusion

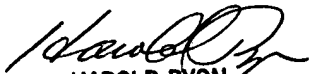
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
10/03/05

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

10/3/05